UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,589	12/22/2000	Leon G. Streit	P04774US0 PHI 1345	8234

27310 7590 12/18/2001

PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

EXAMINER
MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
1638	4

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
09/747 589	STREIT ET AL
Examiner	**Art Unit**
Ashwin Mehta	1638

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION

- Extensions of time may be available under the provisions of 37 CFR 1.136 a [illegible]
after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will by statute cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication even if timely filed may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____

2a)☐ This action is **FINAL** 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
4)☐ Interview Summary (PTO-413) Paper No(s).
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Claim Objections

1. Claims 1, 7, 29, and 46 are objected to for the presence of a blank line where the ATCC Accession No. should be. Inclusion of the number will overcome the objection.

2. Claims 13, 14, 35, and 36 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should only refer to other claims in the alternative only. See MPEP § 608.01(n). Claims 13 and 14 have been examined as if "the inbred soybean plant of claim 2" referred to the plant produced by growing the soybean seed designated 92B84. Claims 35 and 36 have been examined as if "the inbred soybean plant of claim 24" referred to a soybean plant having all of the physiological and morphological characteristics of inbred soybean 92B84. The claims must be amended to be in proper dependent form.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-22, 24-44, and 46-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1-27 of U.S. Patent No. 6,153,816 ('816). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both appear to be drawn to the same soybean seed, plants, and plant parts. The designation "92B84" of the instantly claimed cultivar is arbitrarily assigned, and does not provide any patentable distinction from the cultivar claimed in '816, 93B35. Any differences between 92B84 and 93B35 are due to minor morphological variations that do not confer patentable distinction. Inserting the ATCC Accession No. into the instant claims will overcome the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "92B84" in claims 1, 7, 16, 23, 29, 41, and 45-49 render the claims and those dependent thereon indefinite. Since the name "92B84" is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that denomination. The name "92B84"

does not clearly identify the claimed soybean seed, and does not set forth the metes and bounds of the claimed invention. In addition, the name appears to be arbitrary and the specific characteristics associated therewith could be modified, as there is no claimed description of the soybean plant that encompasses all of its traits. Amending claims 1, 6, 21, 25, 37, and 40 to recite the ATCC deposit number in which seed of maize inbred line PH3PG has been deposited would overcome the rejection.

Further regarding claims 5 and 27: Given that tissue culture can introduce many chromosomal changes in the plant cells, it is not clear exactly what kind of cells comprise the claimed tissue culture. It is suggested that the claim be amended to indicate that the tissue regenerates plants that express all of the morphological and physiological characteristics of soybean variety 92B84.

In claims 9, 20, 31, and 39: the claims are indefinite for improper antecedent basis. The claims are directed to the soybean breeding program of the claim from which they depend. However, the claims from which they depend are directed to a method, not a program.

In claims 10, 21, 22, 27, 32, 40, 44, and 49: the claims are indefinite in that it is unclear what would constitute the soybean plants, given that the methods to produce the plants comprise numerous crosses with plants of unknown characteristics. It is unclear what characteristics the claimed plants and parts thereof possess, as not all traits would be passed on. It is not clear what characteristics the claimed plants and parts thereof possess.

Claims 13 and 14 recite the limitation "the inbred soybean plant" in line 2. There is insufficient antecedent basis for this limitation in the claims, or the claims from which they depend.

In claims 18 and 43: the claims are indefinite form improper antecedence for "the seed of claim 17 (or 42)". The recitation "An F1 hybrid soybean seed plant" also renders the claims indefinite. The plants of claims 17 and 42 are F1 generation plants, as they are produced from the cross of the method of claim 16 or 41. It is then not clear if claims 18 and 43 are referring to the plant of claim 17 or 42, respectively, or a different plant.

In claims 23 and 45, it is not clear which region the listed states are supposed to be a part of. If the states are a part of one of the listed regions, it is suggested that they be deleted, since they would already be encompassed by the claims.

Claim 35 recites the limitation "The method of claim 31 for producing a first generation hybrid soybean seed" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim or the claims from which it depends. Claim 31 improperly is directed to a breeding program (see the rejection above), and is dependent on the method for developing a soybean plant for a soybean breeding program of claim 30. Claim 35 also lacks antecedent basis for "the inbred soybean plant of claim 24".

In claim 48: the recitation "growing said progeny soybean seed of step (a)" renders the claim indefinite. It is not clear if the recitation is referring to step (a) of claim

48, or parent claim 46. Similarly, it is not clear if the reference to steps (a) and (b) in step (c) of claim 48 refers to those steps of claim 48 or claim 46.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 5, 6, 10, 21-23, 27, 28, 32, 40, 44, 45, and 49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims any tissue culture of regenerable cells from soybean plant 92B84; any soybean plant produced from a method for developing a plant for a soybean breeding program, comprising using soybean plant 92B84, or 92B84 transformed to comprise a transgene, or their parts, as one source of breeding material; any soybean plant or its parts, wherein at least one ancestor is 92B84, or wherein the plant shares at least two characteristics with 92B84; any tissue culture of regenerable cells of a plant having all the physiological and morphological characteristics of 92B84; any soybean plant produced by a breeding program using a plant, or its parts, having all the physiological and morphological characteristics of 92B84, as one of its sources, or wherein the plant used as the source is transgenic; any soybean plant that wherein at least one ancestor is a soybean plant produced by crossing a soybean plant having all the morphological and

physiological characteristics of 92B84 further transformed with a transgene, or wherein the soybean plant share at least two traits with 92B84.

The specification describes the phenotype of a soybean plant, arbitrarily given the designation 92B84 (page 10, line 1 to page 12, line 3; page 26, line 1 to page 35, Table 2H). The specification also describes soybean breeding programs, for crop improvement, to derive other soybean varieties or breeding lines, to develop new, unique and superior soybean varieties (page 2, line 14 to page 5, line 35).

However, the specification does not describe any of the plants derived from the breeding programs, or all tissue cultures of soybean variety 92B84. It is well known that chromosome aberrations can be a side effect of tissue culture techniques, which would introduce new characteristics into the tissue culture and in plants regenerated therefrom. The specification does not describe the characteristics of such cultures and plants. It is suggested that claims 5 and 27 be amended to indicate that the regenerable cells of the tissue culture regenerate a plant capable of expressing all of the morphological and physiological characteristics of soybean variety 92B84.

The specification also does not describe the plants that can be produced by the soybean breeding programs, or by crosses wherein at least one ancestor is soybean variety 92B84 or a plant having all of the physiological and morphological characteristics of soybean variety 92B84, wherein the claimed plant is separated form the parent by multiple generations. The description of 92B84 is not indicative of the description of the plant produced by the breeding programs or crosses, as other soybean plants, of unknown genotypes and phenotypes, would be crossed with 92B84 and its progeny. The claims encompass plants that are can be separated by 7 (claim 49), or more generations from

92B84, and which may no longer share any of its traits. Claims 23 and 45 encompass plants that express at least two "92B84 traits." However, to say that a plant expresses two traits of another plant, or has two traits derived from another plant, is not sufficient information to describe that plant, as numerous soybean plants express at least two of the same traits as 92B84. One example is soybean plant 93B85, the subject of U.S. Patent No. 6,153,816. Therefore, to indicate that a plant expresses two 92B84 traits is not a sufficient description of that plant. As numerous plants express traits that are also expressed by 92B84, it is possible that the claimed plants inherited the genes governing those traits from an ancestor other than 92B84. Further information concerning the genotype of 92B84 may distinguish the claimed plants from others expressing at least two 92B84 traits. Such information would indicate that the genetic information governing the expression of the traits had to be derived from 92B84. However, the specification does not provide any description of the genes, molecular markers, etc., of 92B84. Given the breadth of the claims encompassing tissue culture capable of regenerating plants expressing any trait, and soybean plants expressing any trait, or at least two traits that are also expressed by 92B84, and lack of guidance as discussed above, the specification fails to provide an adequate written description of the multitude of soybean plants and their parts encompassed by the claims.

6. Claims 1-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims broadly encompass a plant, or parts thereof, having characteristics of soybean cultivar 92B84, a seed or hybrid derived from cultivar 92B84, soybean plants derived from 92B84, tissue culture derived from 92B84, methods of using said cultivar to produce hybrid soybean seed or progeny, or in a breeding program.

Since the seed claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. It is noted that applicants intend to deposit seeds for 92B84 at the ATCC upon allowance of the claims (specification, page 36, lines 7-10).

If the deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must by maintained.

If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-49 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Steiger et al. (U.S. Patent No. 6,153,816).

The claims broadly encompass a plant, or parts thereof, having characteristics of soybean cultivar 92B84, a seed or hybrid derived from cultivar 92B84, soybean plants derived from 92B84, tissue culture derived from 92B84, methods of using said cultivar to produce hybrid soybean seed or progeny, or in a breeding program.

Steiger et al. teaches seed of soybean variety 93B35, plants produced by growing said seed, and plants and plant parts having all of the physiological and morphological characteristics of soybean 93B35. It appears that the claimed plants and seeds of the instant invention may be the same as 93B35, given that each has a black hilum color, brown pod color, demonstrates very good yield, very good tolerance to Brown Stem Rot, a substantial degree of glyphosate resistance, and is particularly suited to the Plains, Southern Plains, and Eastern regions of the United States, for example (Table 1; col. 7, line 63 to col. 8, line 7). Alternatively, if the claimed plants, plant parts, and seeds of 92B84 are not identical to 93B35, then it appears that 93B35 only differs from the claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the

same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to 92B84. Steiger et al. also teach production of tissue culture of regenerable cells from a plant of line 93B35, a plant produced from tissue culture of 93B35, methods for producing hybrid seed and plants wherein a plant of inbred line 93B35 is crossed with itself or another soybean plant, and soybean plant pedigree breeding (col. 1, line 52 to col. 3, line 5; col. 7, lines 40-52; col. 17, line 23 to col. 18, line 14). Introduction of other genes into 93B35 via genetic engineering or breeding is also taught, as well as crossing the transformed plant with another plant to produce progeny comprising the inherited transgene (col. 8, line 60 to col. 17, line 22). As cultivar 93B35 is the same as cultivar 93B35, the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Steiger et al. Amending claims 1, 7, 29, and 46 to include the ATCC accession number will overcome the rejection for claims 1-9, 11-20, 24-26, 28-31, 33-39, 41-43, and 46-48.

However, inclusion of the ATCC number would not overcome the rejection for claims 10, 21-23, 27, 32, 40, 44, 45, and 49, as they are drawn to plants or parts thereof that possess any traits, or at least two of the traits of the plants of Steiger et al. The process of making the claimed plants does not distinguish the plants themselves from those taught by the reference. Thus, the claimed invention was clearly *prima facie* obvious as a whole to one of ordinary skill in the art, if not anticipated by Steiger et al.

8. No claim is allowed.

Contact Information

Any inquiry concerning this communication from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on 703-308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A.M.
December 17, 2001

AMY J. NELSON, PH.D
PRIMARY EXAMINER